

The Role of Laboratory Accreditation (and Conformity Assessment) in the Marketplace

August 2004



National Voluntary Laboratory Accreditation Program



Jeffrey Horlick

**National Institute of Standards and Technology
National Voluntary Laboratory Accreditation Program
(NIST / NVLAP)**

**Building 820 Room 293
100 Bureau Drive Stop 2140
Gaithersburg, MD 20899-2140**

Phone: 301.975.4020

Fax: 301.926.2884

E-mail: jeffrey.horlick@nist.gov

URL: <http://www.nist.gov/nvlap>



Why Laboratory Accreditation (and Conformity Assessment)?

- So you don't have to worry.
 - Confidence - it has been done right
 - Competence - get the right answer
 - Equivalence - get the same answer
 - Independence - nothing else is going on
 - Appropriateness - fit for purpose

Why Harmonization?

- So you can talk to each other
- So you can do business with each other

Vocabulary

- Conformity Assessment –
any activity concerned with determining directly or indirectly that relevant requirements are fulfilled

Note: Typical examples of conformity assessment activities are sampling, testing and inspection; evaluation, verification and assurance of conformity (supplier's declaration, certification); registration, accreditation and approval as well as their combinations.

ISO/IEC Guide 2:1996

Vocabulary

- Harmonized Standards –
equivalent standards
standards on the same subject approved by different
standardizing bodies, that establish interchangeability
of products, processes and services, or mutual
understanding of test results or information provided
according to these standards.

Note: Within this definition, harmonized standards might have differences in presentation and even in substance, e.g. in explanatory notes, guidance on how to fulfill the requirements of the standard, preferences for alternatives and varieties.

ISO/IEC Guide 2:1996

My Vocabulary

- Accreditation of -
 - testing laboratories
 - calibration laboratories
 - inspection bodies
- Registration of -
 - quality management systems (QMS)
 - environmental management systems (EMS)
- Certification of -
 - products
 - people

My Vocabulary

- Assessment

- determination of a laboratory's competence and conformance to standards by a laboratory accreditation body
- required for accreditation

- Evaluation

- determination of a laboratory accreditation body's conformance to standards by its peers
- required for MRAs

World Trade Organization (WTO)

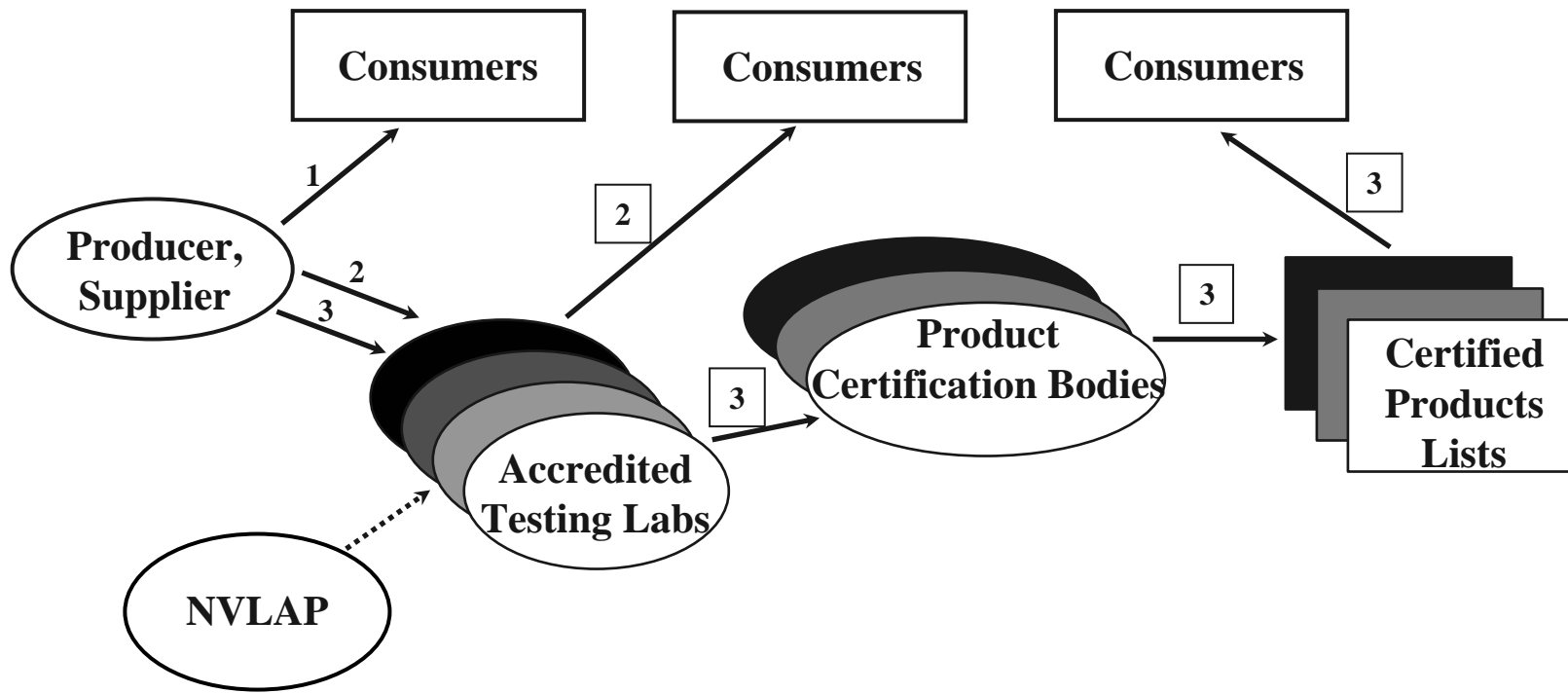
- Final Act - Agreement Establishing the World Trade Organization
- Annex 1 - Multilateral Agreements on Trade in Goods
- Agreement on Technical Barriers to Trade
 - Article 5 - Procedures for Assessment of Conformity by Central Government Bodies
 - Article 6 - Recognition of Conformity Assessment by Central Government Bodies

http://www.wto.org/wto/english/docs_e/legal_e/legal_e.htm

What is NVLAP?

- A process for accreditation of testing and calibration laboratories
- Established in the U.S. Code of Federal Regulations (Title 15, Part 285) in 1976
- Administered by NIST
- Linked to NIST research units
- Based on international (ISO/IEC) standards
- Available to any qualifying laboratory (public or private)
- Fee supported
- Signatory to several international MRAs
- 800+ labs in the system today

Paths to Consumer

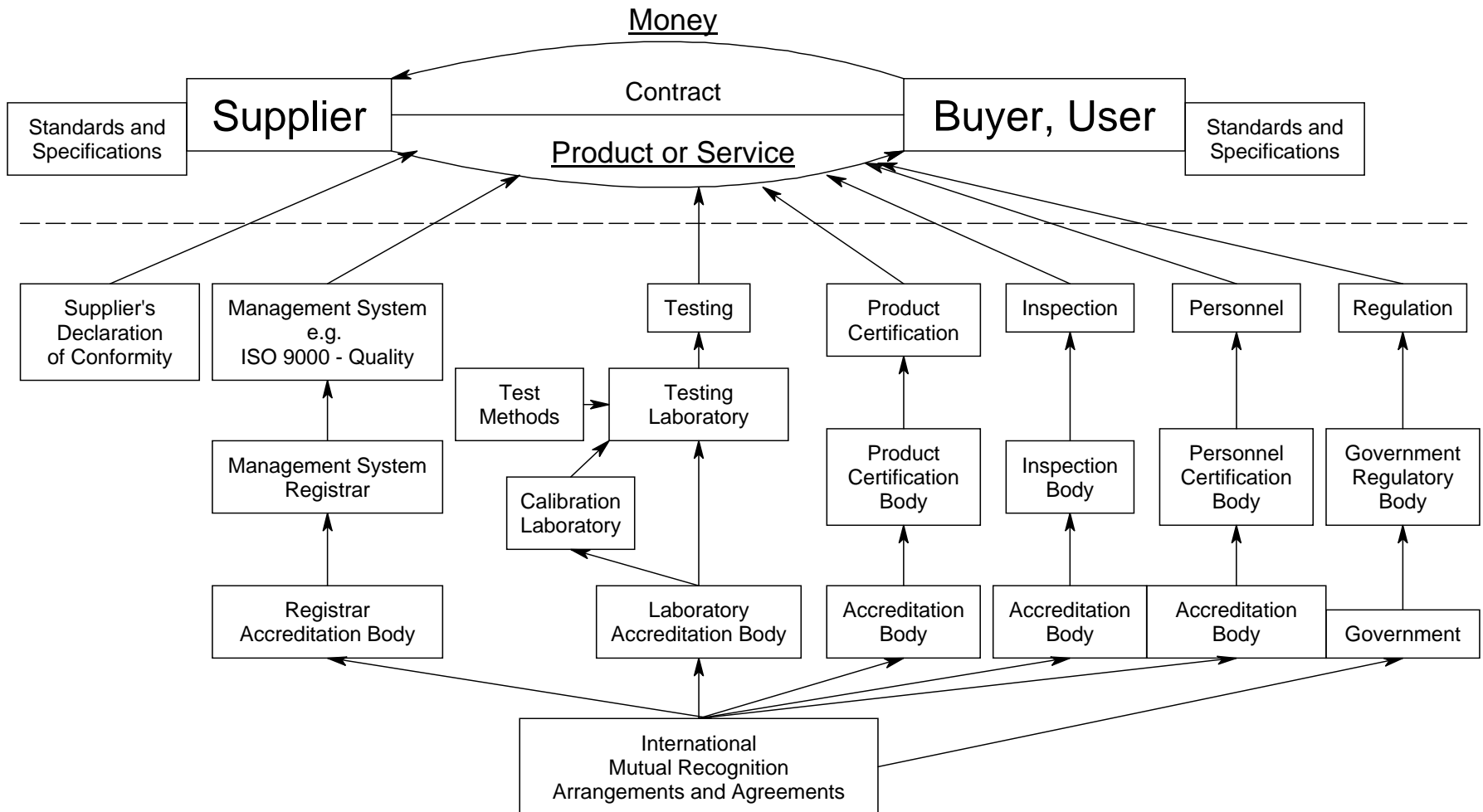


Path 1: Declaration of Conformity

Path 2: Conformance demonstrated by testing in accredited laboratory

Path 3: Conformance demonstrated by testing and product certification

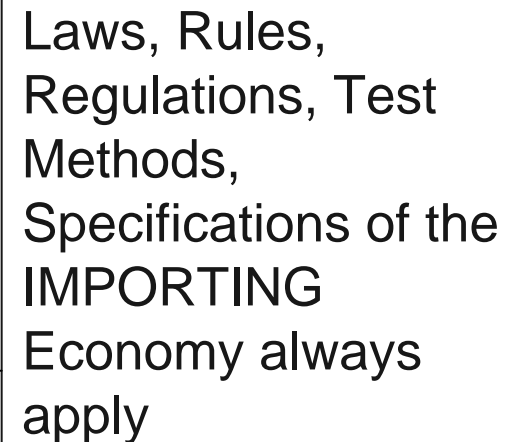
DOMESTIC AND INTERNATIONAL TRADE



CONFORMITY ASSESSMENT

jh-20031218

Test Anywhere - Sell Anywhere



International Mutual Recognition Arrangements (MRA)

World MRAs:

- International Laboratory Accreditation Cooperation (ILAC)
for testing and calibration laboratories
<<http://www.ilac.org/>>
- International Accreditation Forum (IAF)
for QMS, EMS, and product certification
<<http://www.iafinc.org>>

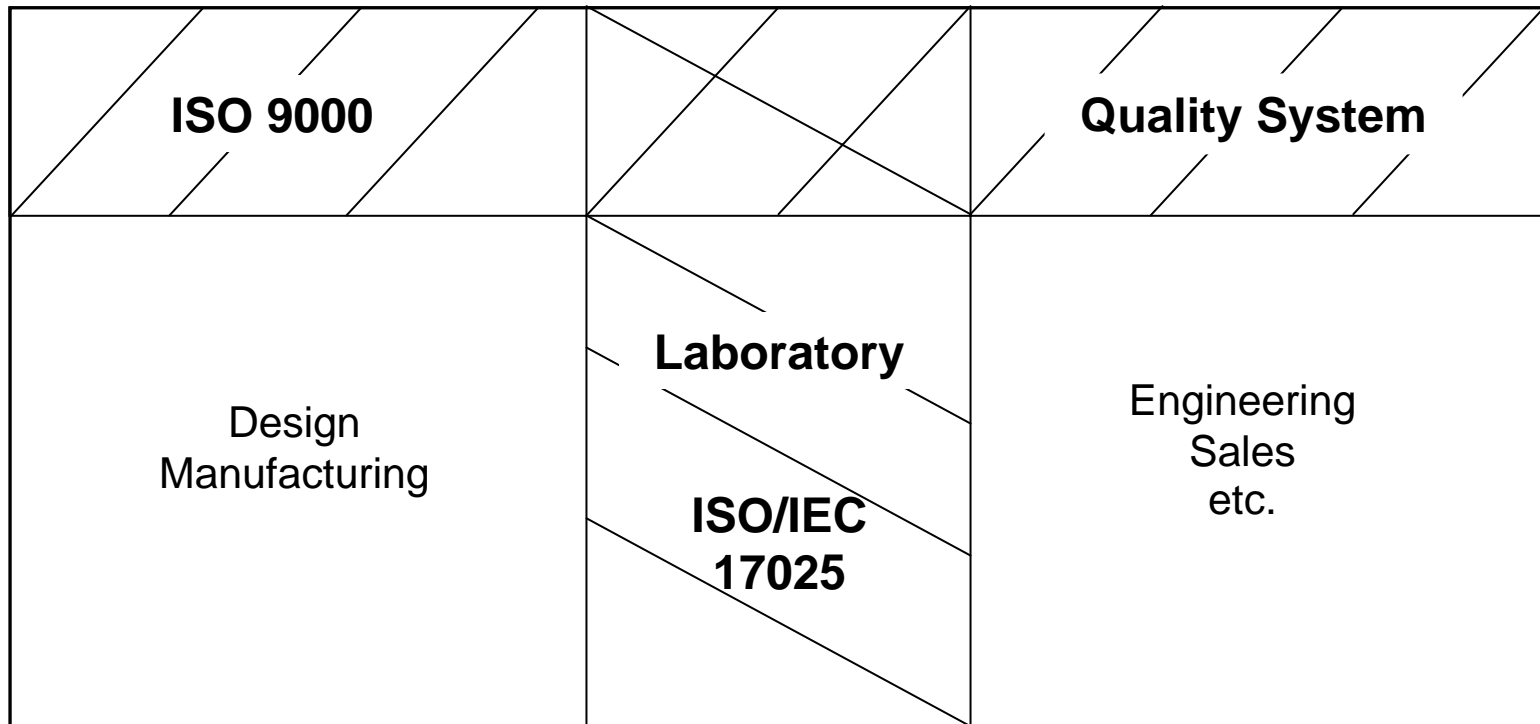
(Quality Management System, Environmental Management System)

Conformity Assessment - ISO Guides and Standards

Testing and Calibration Laboratories 1	Product Certification Bodies 2	Management Systems Registrars - Quality and Environment 3	Inspection Bodies 4	
Mutual Recognition Arrangement (ILAC P1, APLAC MR001, EA-2/02)	Multilateral Recognition Arrangement (IAF MLA P&P3)	Multilateral Recognition Arrangement (IAF MLA P&P3)	Mutual Recognition Arrangement (APLAC MR001, EA-2/02)	A
Accreditation Bodies (ISO/IEC Guide 58:1993)	Accreditation Bodies (ISO/IEC Guide 61:1996)	Accreditation Bodies (ISO/IEC Guide 61:1996)	Accreditation Bodies (ISO/IEC TR 17010:1998)	B
Accredited testing and calibration laboratories (ISO 17025:1999 previously ISO/IEC Guide 25)	Product certification Bodies (ISO/IEC Guide 65:1996)	Registrars (ISO/IEC Guide 62:1996, ISO/IEC Guide 66:1999)	Inspection Bodies (ISO 17020:1998)	C
Samples (Test methods and sampling methods)	Products and services (Appropriate product or service standards)	Companies or organizations (ISO 9000, ISO 14000, or equivalent)	Products (Appropriate product standards)	D

ISO 9000 and ISO/IEC 17025

ISO 9000 is a stripe across the top of an organization



**ISO/IEC 17025 is stripe from top to bottom
covering the entire laboratory**

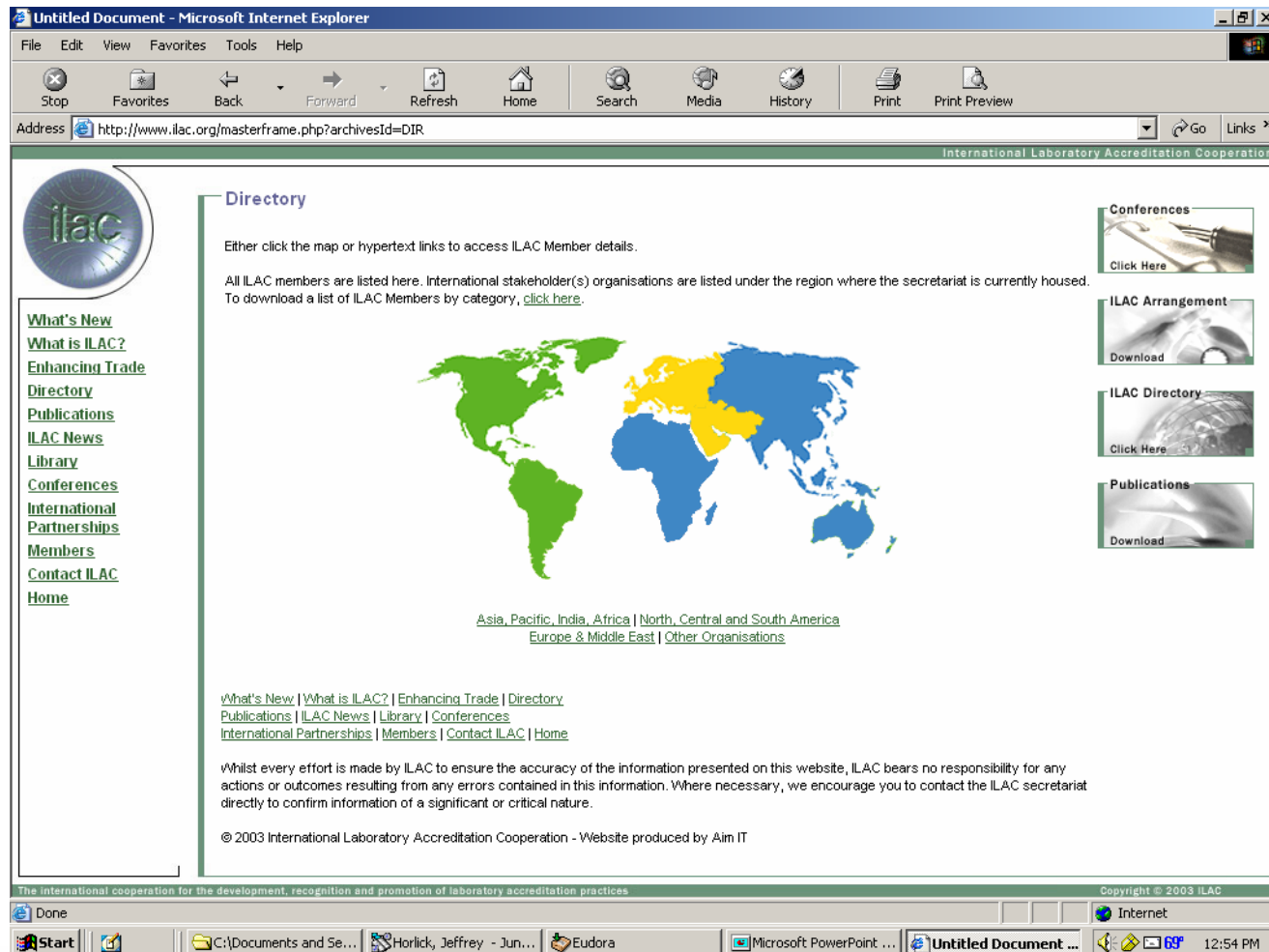
National Cooperation for Laboratory Accreditation (NACLA) - USA

- NACLA is a nonprofit corporation established to coordinate laboratory accreditation activities within the United States and to serve as the U.S. link to the worldwide lab accreditation system.
- NACLA is a partnership of the public and private sectors.
- Any Organization with an interest in laboratory accreditation is eligible for NACLA membership.
- There is a NACLA Mutual Recognition Arrangement for accreditation bodies that meet the criteria.

[<http://www.nacla.net/>](http://www.nacla.net/)

ILAC Directory

<http://www.ilac.org/directory.htm>



ILAC Brochures

<http://www.ilac.org/> see Publications

- Why Use An Accredited Laboratory?
- Why Become An Accredited Laboratory?
- How Does Using an Accredited Laboratory Benefit Government & Regulators?
- The Advantages of Being An Accredited Laboratory

available in English, Russian, Japanese, Spanish, Chinese